The opinion in support of the decision being entered today was <u>not</u> written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte GREGORY DONOHO, JOHN SCOVILLE, C. ALEXANDER TURNER, JR., GLENN FRIEDRICH, BRIAN ZAMBROWICZ and ARTHUR T. SANDS

Appeal No. 2004-1103 Application No. 09/733,387

ON BRIEF

MAILED

JUN 3 0 2004

U.S. PATENT AND TRADEMARK OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES

Before SCHEINER, ADAMS, and GRIMES, <u>Administrative Patent Judges</u>.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-3 and 6-7, which are all the claims pending in the application.

Claim 1 is illustrative of the subject matter on appeal and is reproduced below:

 An isolated nucleic acid molecule comprising at least 22 contiguous bases of nucleotide sequence from SEQ ID NO:43.

The references relied upon by the examiner are:

Bork et al. (Bork), "Predicting functions from protein sequences – where are the bottlenecks?" Nature Genetics, Vol. 18, pp. 313-318 (1998)

Ji et al. (Ji), "G-protein-coupled receptors," <u>J. Biol. Chem.</u>, Vol. 273, pp. 17299-302 (1998)

Yan et al. (Yan), "Two-Amino Acid Molecular Switch in an Epithelial Morphogen That Regulates Binding to Two Distinct Receptors," <u>Science</u>, Vol. 290, pp. 523-27 (2000)

GROUNDS OF REJECTION

Claims 1-3 and 6-9 stand rejected under 35 U.S.C. § 101 as lacking utility and § 112, first paragraph, for lack of enablement based on the finding of lack of utility.

Claim 1¹ stands rejected under both the enablement and written description provisions of 35 U.S.C. § 112, first paragraph.

We affirm the rejection under 35 U.S.C. § 101 as lacking utility and § 112, first paragraph, for lack of enablement based on the finding of lack of utility. Having disposed of all claims on appeal we do not reach the merits of the separate rejection of claim 1 under both the enablement and written description provisions of 35 U.S.C. § 112, first paragraph.

We note the confusion relating to the claim under rejection. The examiner's statement of the rejections refer only to claim 1. See Answer, bridging paragraph, pages 7-8 and page 9, first paragraph. Appellants, however, have interpreted the rejections as applying to claims 1 and 6-9. See e.g., Brief, page 4, Section VI. Nevertheless, the examiner clarified (Answer, page 2, Section 6) that claims 7 and 8 are not part of this rejection. Upon consideration of the Final Rejection, we note again that claim 1 is the only claim discussed. Accordingly, we find that claim 1 is the only claim properly rejected under this ground of rejection. Cf. Paperless Accounting, Inc. v. Bay Area Rapid Transit Sys., 804 F.2d 659, 663, 231 USPQ 649, 651 (Fed. Cir. 1986) ("[MPEP §] 707.07(e) Note all Outstanding Requirements[:] ... Every point in the prior action of an examiner which is still applicable must be repeated or referred to, to prevent the implied waiver of the requirement" [emphasis removed]).

Claim Grouping

The claims stand or fall together. Brief, page 4. Since all claims stand or fall together, we limit our discussion to representative independent claim 1.

Claims 2, 3 and 6-9 will stand or fall together with claim 1. In re Young, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991).

<u>BACKGROUND</u>

The examiner finds (Answer, page 4), "[t]he specification asserts that the nucleic acid sequences of the present invention encode human GPCRs [(G protein-coupled receptors²)] because the proteins encoded by the present nucleic acid sequences have structural motifs found in the GPCRs family...." As set forth in the specification (page 2), GPCRs "are transmembrane proteins that span the cellular membrane and are involved in signal transduction after ligand binding." According to Ji (page 17299, column 1, first paragraph), GPCRs "are classified into over 100 subfamilies according to the[ir] sequence homology, ligand structure, and receptor function. A substantial degree of amino acid homology is found among members of a particular subfamily, but comparisons between subfamilies show significantly less or no similarity."

² We note that appellants refer to the GPCR of their invention as a "novel GPCR (NGPCR)." <u>See e.g.</u>, Specification, page 2, lines 6-11.

DISCUSSION

The examiner rejected all of the claims as lacking patentable utility.³ The examiner bears the initial burden of showing that a claimed invention lacks patentable utility. See In re Brana, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) ("Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility.").

The seminal decision interpreting the utility requirement of § 101 is Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966). At issue in Brenner was a claim to "a chemical process which yields an already known product whose utility—other than as a possible object of scientific inquiry—ha[d] not yet been evidenced." Id. at 529, 148 USPQ at 693. The Patent Office had rejected the claimed process for lack of utility, on the basis that the product produced by the claimed process had not been shown to be useful. See id. at 521-22, 148 USPQ at 690. On appeal, the Court of Customs and Patent Appeals reversed, on the basis that "where a claimed process produces a known product it is not necessary to show utility for the product." Id. at 522, 148 USPQ at 691.

³ The examiner rejected the claims under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph. However the rejection for nonenablement was presented simply as a corollary of the finding of lack of utility. <u>See</u> Answer, page 7. Therefore, although we discuss only the § 101 rejection, our conclusion also applies to the § 112 rejection.

The <u>Brenner</u> Court noted that although § 101 requires that an invention be "useful," that "simple, everyday word can be pregnant with ambiguity when applied to the facts of life." <u>Id.</u> at 529, 148 USPQ at 693. Thus,

[it] is not remarkable that differences arise as to how the test of usefulness is to be applied to chemical processes. Even if we knew precisely what Congress meant in 1790 when it devised the "new and useful" phraseology and in subsequent re-enactments of the test, we should have difficulty in applying it in the context of contemporary chemistry, where research is as comprehensive as man's grasp and where little or nothing is wholly beyond the pale of "utility"—if that word is given its broadest reach.

ld. at 530, 148 USPQ at 694.4

The Court, finding "no specific assistance in the legislative materials underlying § 101," based its analysis on "the general intent of Congress, the purposes of the patent system, and the implications of a decision one way or the other." Id. at 532, 148 USPQ at 695. The Court concluded that "[t]he basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." Id. at 534-35, 148 USPQ at 695.

The Court considered and rejected the applicant's argument that attenuating the requirement of utility "would encourage inventors of new

⁴ The invention at issue in <u>Brenner</u> was a process, but the Court expressly noted that its holding "would apply equally to the patenting of the product produced by the process." <u>Id.</u> at 535, 148 USPQ at 695-96.

processes to publicize the event for the benefit of the entire scientific community, thus widening the search for uses and increasing the fund of scientific knowledge." The Court noted that, while there is value to encouraging disclosure, "a more compelling consideration is that a process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development." Id. at 534, 148 USPQ at 695.

The Court took pains to note that it did not "mean to disparage the importance of contributions to the fund of scientific information short of the invention of something 'useful,'" and that it was not "blind to the prospect that what now seems without 'use' may tomorrow command the grateful attention of the public." Id. at 535-36, 148 USPQ at 696. Those considerations did not sway the Court, however, because "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." Id.

Subsequent decisions of the CCPA and the Court of Appeals for the Federal Circuit have added further layers of judicial gloss to the meaning of § 101's utility requirement. The first opinion of the CCPA applying <u>Brenner</u> was <u>In re Kirk</u>, 376 F.2d 936, 153 USPQ 48 (CCPA 1967). The invention claimed in Kirk was a set of steroid derivatives said to have valuable biological properties

and to be of value "in the furtherance of steroidal research and in the application of steroidal materials to veterinary or medical practice." Id. at 938, 153 USPQ at 50. The claims had been rejected for lack of utility. In response, the applicants submitted an affidavit which purportedly "show[ed] that one skilled in the art would be able to determine the biological uses of the claimed compounds by routine tests." Id. at 939, 153 USPQ at 51.

The court held that "nebulous expressions [like] 'biological activity' or 'biological properties'" did not adequately convey how to use the claimed compounds. <u>Id.</u> at 941, 153 USPQ at 52. Nor did the applicants' affidavit help their case: "the sum and substance of the affidavit appear[ed] to be that one of ordinary skill in the art would know 'how to use' the compounds to find out in the first instance whether the compounds are—or are not—in fact useful or possess useful properties, and to ascertain what those properties are." <u>Id.</u> at 942, 153 USPQ at 53.

The <u>Kirk</u> court held that an earlier CCPA decision, holding that a chemical compound meets the requirements of § 101 if it is useful to chemists doing research on steroids, had effectively been overruled by <u>Brenner</u>. "There can be no doubt that the insubstantial, superficial nature of vague, general disclosures or arguments of 'useful in research' or 'useful as building blocks of value to the researcher' was recognized, and clearly rejected, by the Supreme Court" in <u>Brenner</u>. <u>See Kirk</u>, 376 F.2d at 945, 153 USPQ at 55.

More recently, in <u>In re Ziegler</u>, 992 F.2d 1197, 26 USPQ2d 1600 (Fed. Cir. 1993), the Federal Circuit considered the degree of specificity required to show

utility for a claim to polypropylene. The U.S. application on appeal in Ziegler claimed priority to a German application filed in 1954. "In the German application, Ziegler disclosed only that solid granules of polypropylene could be pressed into a flexible film with a characteristic infrared spectrum and that the polypropylene was 'plastic-like.'" Id. at 1203, 26 USPQ2d at 1605. "Ziegler did not assert any practical use for the polypropylene or its film, and Ziegler did not disclose any characteristics of the polypropylene or its film that demonstrated its utility." Id. The court held that the German application did not satisfy the requirements of § 101 and therefore could not be relied on to overcome a rejection based on an intervening reference. See id., 26 USPQ2d at 1606. "[At] best, Ziegler was on the way to discovering a practical utility for polypropylene at the time of the filing of the German application; but in that application Ziegler had not yet gotten there." Id., 26 USPQ2d at 1605.

On the other hand, the CCPA reversed a rejection for lack of utility in In re Jolles, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980). The applicant in Jolles claimed pharmaceutical compositions that were disclosed to be useful in treating acute myeloblastic leukemia. See id. at 1323, 206 USPQ at 886. The active ingredients in the compositions were closely related to daunorubicin and doxorubicin, both of which were "well recognized in the art as valuable for use in cancer chemotherapy." Id., 206 USPQ at 887. The applicant also submitted declaratory evidence showing that eight of the claimed compositions were effective in treating tumors in a mouse model, and one was effective in treating humans. See id. at 1323-24, 206 USPQ at 887-88. The court noted that the

data derived from the mouse model were "relevant to the treatment of humans and [were] not to be disregarded," <u>id.</u> at 1327, 206 USPQ at 890, and held that the evidence was sufficient to support the asserted therapeutic utility. <u>See id.</u> at 1327-28, 206 USPQ at 891.

The Federal Circuit held in Cross v. lizuka, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985), that in vivo testing (as in Jolles) was not necessarily required to show utility in the pharmaceutical context. The Cross court stated that "[it] is axiomatic that an invention cannot be considered 'useful,' in the sense that a patent can be granted on it, unless substantial or practical utility for the invention has been discovered and disclosed where such utility would not be obvious." Id. at 1044, 224 USPQ at 742 (citing Brenner v. Manson). The court "perceive[d] no insurmountable difficulty, under appropriate circumstances, in finding that the first link in the screening chain, in vitro testing, may establish a practical utility for the compound in question." Id. at 1051, 224 USPQ at 748. Successful in vitro testing could provide an immediate benefit to the public, by "marshal[ling] resources and direct[ing] the expenditure of effort to further in vivo testing of the most potent compounds . . ., analogous to the benefit provided by the showing of an in vivo utility." Id. On the facts of that case - successful in vitro testing supplemented by similar in vitro and in vivo activities of structurally similar compounds - the court held that in vitro activity was sufficient to meet the requirements of § 101. See id.

The Federal Circuit confirmed in <u>In re Brana</u>, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995), that human testing is not necessary to establish utility for

Appeal No. 2004-1103 Application No. 09/733,387

a method of treatment. The invention claimed in <u>Brana</u> was a group of compounds disclosed to have antitumor activity. <u>See id.</u> at 1562, 34 USPQ2d at 1437-38. The specification disclosed that the claimed compounds had higher antitumor activity than related compounds known to have antitumor activity, and the applicants provided declaratory evidence of <u>in vivo</u> activity against tumors in a mouse model. <u>See id.</u>, 34 USPQ2d at 1438. The court held that these data were sufficient to satisfy § 101; usefulness in patent law does not require that the invention be ready to be administered to humans. <u>See id.</u> at 1567, 34 USPQ2d at 1442.

Several lessons can be drawn from Brenner and its progeny. First, § 101's requirement that an invention be "useful" is not to be given its broadest reach, such that little or nothing of a chemical nature would be found to lack utility. See Brenner, 383 U.S. at 530, 148 USPQ at 694. Thus, not every "use" that can be asserted will be sufficient to satisfy § 101. For example, the steroid compound at issue in Brenner was useful as a possible object of scientific inquiry, and the polypropylene claimed in Ziegler was useful for pressing into a flexible film, yet both lacked sufficient utility to satisfy § 101. See Brenner, 383 U.S. at 529, 148 USPQ at 696; Ziegler, 992 F.2d at 1203, 26 USPQ2d at 1605.

Rather than setting a <u>de minimis</u> standard, § 101 requires a utility that is "substantial", i.e., one that provides a specific benefit in currently available form. <u>Brenner</u>, 383 U.S. at 534-35, 148 USPQ at 695. This standard has been found to be met by pharmaceutical compositions shown to be useful in mouse models and in humans for treating acute myeloblastic leukemia (<u>Jolles</u>, 628 F.2d at

1327-28, 206 USPQ at 891); by evidence showing successful in vitro testing supplemented by similar in vitro and in vivo activities of structurally similar compounds (Cross, 753 F.2d at 1051, 224 USPQ at 748); and by evidence showing in vivo antitumor activity in mice, combined with a disclosure that the claimed compounds had higher antitumor activity than a related compound known to have antitumor activity (Brana, 51 F.3d at 1567, 34 USPQ2d at 1442).

By contrast, <u>Brenner's</u> standard has been interpreted to mean that "vague, general disclosures or arguments of 'useful in research' or 'useful as building blocks of value to the researcher" would not satisfy § 101. <u>See Kirk,</u> 376 F.2d at 945, 153 USPQ at 55 (interpreting <u>Brenner</u>). Likewise, a disclosure of a "plastic-like" polypropylene capable of being pressed into a flexible film was held to show that the applicant was "at best . . . on the way to discovering a practical utility for polypropylene at the time of the filing," but not yet there. Ziegler, 992 F.2d at 1203, 26 USPQ2d at 1605.

On this record, the examiner finds (Answer, page 4),

there is no disclosure of the ligand(s), biological functions, or any physiological significance of the putative GPCRs; there is no disclosure of any evidence indicating that the putative GPCRs are truly functional GPCRs and are involved in [a] signal transduction pathway involving G-proteins or PPG proteins as ... asserted; there is no disclosure of any evidence indicating that the claimed nucleic acid sequences are expressed at altered levels or forms in any specific[] diseased tissue, as compared with the [sic] healthy control tissue. Thus, the claimed nucleic acid molecules lack a specific and substantial utility.

We agree with the examiner that the specification's disclosure is inadequate to provide a substantial utility for the claimed invention. As the

examiner points out (Answer, bridging paragraph, pages 5-6), the disclosed utilities⁵ for the claimed nucleic acid molecule, and the polypeptide encoded thereby, amount to no more than research on the claimed invention itself. Because the specification fails to disclose the biological activity of the protein encoded by the claimed nucleic acids, none of the disclosed utilities that depend on that biological activity could be practiced without the expectation of a great deal of further experimentation. Cf. Answer, full paragraph, page 6. Thus, the specification does not provide a specific utility for the claimed invention, in currently available form.

According to appellants (Brief, page 9), the claimed nucleic acid molecule can be used in methods that do not depend on the biological activity of the encoded protein. For example, appellants argue that the claimed nucleic acid can be used in "gene chips" or "DNA chips" to analyze the level of gene expression. See Brief, pages 8-9 (emphasis in original):

Such "DNA chips" clearly have utility, as evidenced by hundreds of issued U.S. Patents.... Clearly, compositions that <u>enhance</u> the utility of such DNA chips, such as the presently claimed nucleotide sequences, must in themselves be useful.

Appellants also assert (Brief, page 10), the claimed nucleotide sequences have "utility in 'determining the genomic structure' of the allele encoding the presently claimed sequence." According to appellants (<u>id.</u>), "the claimed

⁵ According to the examiner (Answer, pages 5-6), appellants' specification asserts that the claimed nucleic acid sequence is useful for regulating gene expression, as hybridization probes for screening libraries, in determining genome structure, as part of gene chips, in the generation of antibodies to the protein encoded by the claimed nucleic acid molecule, to identify mutations associated with a particular disease, for the treatment of diseases and to screen for agonists, antagonists and drugs.

polynucleotide sequence defines how the encoded exons are actually spliced together to produce an active transcript (i.e., the described sequences are useful for functionally defining exon splice-junctions)." In addition, appellants assert (Brief, page 11), "the present polynucleotide provides exquisite specificity in localizing the specific region of human chromosome 16 that contains the gene encoding the given polynucleotide...."

These arguments are not persuasive. The asserted uses of the claimed nucleic acid molecule—as a component of a DNA chip for monitoring gene expression, as a marker for a given chromosomal locus, or for defining the exon splice-junctions of a gene—do not satisfy the utility requirement of § 101, because such uses do not provide a specific benefit in currently available form.

For example, with regard to the asserted "DNA chip" utility, we accept for argument's sake that a person skilled in the art could attach the nucleic acid molecule of claim 1 to a solid substrate, in combination with other polynucleotides, to form a DNA chip. We can also accept that such a DNA chip could be used to monitor changes in expression of the corresponding gene. However, the specification provides no guidance to allow a skilled artisan to use data relating to the expression of the corresponding gene in any practical way. The specification provides no guidance regarding what the GPCR gene-specific information derived from a DNA chip would mean.

Assume, for example, that the nucleic acid molecule of claim 1 was attached to a DNA chip and the researcher observed that expression of the corresponding gene was increased when a cell was treated with a particular

agent. The specification provides no basis on which a skilled worker would be able to determine whether that result is meaningful. Maybe the meaning in a change in expression of the gene would depend on other factors, but again the specification provides no hint what other factors might be important. Would it depend on what agent is used, the cell type used, the behavior of other genes (if so, which genes and what behavior is significant), the degree of increase? Because the specification provides no information about the activity of the protein encoded by the claimed nucleic acid molecule, it provides no guidance as to how to interpret the results of a DNA chip-based gene expression assay based on the claimed nucleic acid molecule.

The same problem afflicts appellants' assertions that the claimed nucleic acid molecule can be used to map a particular chromosomal locus or to define the exon splice-junctions of the genomic gene. The specification provides no meaningful guidance regarding how to use such information in any practical way. Assume, for example, that a nucleic acid molecule of claim 1 hybridizes to a specific part of human chromosome 16, or that this nucleic acid molecule can be used to show that the chromosomal gene has an exon splice junction; the specification provides no guidance on how such information would allow those skilled in the art to use the claimed nucleic acid molecule in a specific, substantial way. By contrast, if the specification disclosed, for example, that a nucleic acid molecule of claim 1 hybridized adjacent to a chromosomal locus associated with a known disease (e.g., a locus susceptible to a cancer-causing translocation), the sequence would have an apparent utility in disease diagnosis.

However, without disclosure of a specific use for the resulting data, using the claimed nucleic acid molecule for mapping or determining exon splice-junctions amounts to research on the claimed nucleic acid molecule itself.

In effect, appellants' position is that the claimed nucleic acid molecule is useful because those of skill in the art could experiment with it and figure out for themselves what any observed experimental results might mean. We do not agree that such a disclosure provides a "specific benefit in currently available form." Rather, the instant case seems analogous to Brenner. In Brenner, the applicant claimed a method of making a compound but disclosed no utility for the compound. 383 U.S. at 529, 148 USPQ at 693. The Court held that a process lacks utility if it produces a product that lacks utility. Id. at 534, 148 USPQ at 695. Here, appellants claim a product asserted to be useful in a method of generating gene-expression or gene-mapping data, but the specification does not disclose how to interpret those data. Just as the process claimed in Brenner lacked utility because the specification did not disclose how to use the endproduct, the product claims here lack utility, based on their use in, e.g., DNA chips, because the specification does not disclose how to use the GPCR genespecific gene expression data generated by a DNA chip.

Further, regarding appellants' assertion that the claimed nucleic acid molecule could potentially be part of a DNA chip; since DNA chips have utility, compounds that "enhance the utility of such DNA chips, such as the presently claimed nucleotide sequences, must in themselves be useful." Brief, page 9 (emphasis original). We disagree. Assuming arguendo that a generic DNA

chip—one comprising a collection of uncharacterized or semi-characterized gene fragments—would provide a useful tool for, e.g., drug discovery, it does not follow that each one of the polynucleotides represented in the DNA chip individually has patentable utility. Although each polynucleotide on the DNA chip contributes to the data generated by the DNA chip overall, the contribution of a single polynucleotide—its data point—is only a tiny contribution to the overall picture.

The <u>Brenner</u> Court held that § 101 sets more than a <u>de minimis</u> standard for utility. Therefore, the patentable utility of a DNA chip, for example, does not necessarily mean that each component of the DNA chip also has patentable utility. A patentable utility divided by a thousand does not necessarily equal a thousand patentable utilities. <u>Each</u> claimed invention must be shown to meet § 101's utility requirement in order to be patentable; it must provide a specific benefit in currently available form. Providing a single data point among thousands or millions, even if the thousands or millions of data points <u>collectively</u> are useful, does not meet this standard.

The Supreme Court noted that the patent system contemplates a basic quid pro quo: in exchange for the legal right to exclude others from his invention for a period of time, an inventor discloses his invention to the public. See Brenner, 383 U.S. at 534, 148 USPQ at 695. The Brenner Court held that the grant of patent rights to an applicant is justified only by disclosure of an invention with substantial utility – a specific benefit in currently available form. Until the invention has been refined and developed to this point, the Court held, the

applicant has not met his side of the bargain, and has not provided a disclosure that justifies granting him the right to exclude others. <u>See id.</u>

In this case, appellants seek the right to exclude others from using a nucleic acid molecule comprising at least 22 contiguous bases of the nucleotide sequence set forth in SEQ ID NO: 43. In return, appellants contend that they need not disclose the biological role or activity of the encoded protein. See e.g., appellants' assertion (Brief, page 11, emphasis original), "[e]xpression profiling does not require a knowledge of the function of the particular nucleic acid on the chip...." We do not agree that such a disclosure satisfies § 101. The basic quid pro quo of the patent system, as interpreted by the Brenner Court, is the grant of a valuable legal right in exchange for a meaningful disclosure of the claimed invention. The generic utilities disclosed for the claimed product in this case do not entitle appellants to the legal right they claim.

We note that this application is one of several on appeal that share the same assignee. In each of these applications, regardless of the specific facts of the case, appellants have argued that the claimed nucleic acid molecule can be used in DNA chips. It would therefore appear that appellants are using the asserted DNA chip utility as a stalking horse, to provide a utility that can be asserted for any cDNA they isolate, regardless of how little is known about it, which (they hope) will nonetheless serve as a basis for patent protection of all related products and methods and secure for appellants any value that might

the claimed products. This is precisely the type of result that the <u>Brenner Court</u> sought to avoid by requiring disclosure of a substantial utility to satisfy § 101.

See 148 U.S. at 535-36, 148 USPQ at 696: [The Court was not] "blind to the prospect that what now seems without 'use' may tomorrow command the grateful attention of the public. But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." <u>Id.</u>

The nucleic acid molecule of claim 1 may indeed prove to be useful (and valuable), after the <u>in vivo</u> role of the encoded protein is discovered. The work required to confer value on the claimed products, however, remains to be done. The instant specification's disclosure does not justify a grant of patent rights.

See Brenner, 383 U.S. at 534, 148 USPQ at 695: "[A] process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development." We consider the <u>Brenner</u>

⁶ The applications referred to are: 09/460,594 (Appeal No. 2003-1528), 09/804,969 (2003-1794); 09/802,116 (2003-2017); 09/822,807 (2003-2028); 09/564,557 (2004-0343); 09/934,451 (2004-0400).

Appeal No. 2004-1103 Application No. 09/733,387

Court's concern about the "power to block off whole areas of scientific development" to be equally applicable here.

For the foregoing reasons, we affirm the rejection of claim 1 under 35 U.S.C. § 101 as lacking utility and § 112, first paragraph, for lack of enablement based on the finding of lack of utility. As discussed <u>supra</u> claims 2, 3 and 6-9 fall together with claim 1. Having disposed of all claims on appeal we do not reach the merits of the separate rejection of claim 1 under both the enablement and written description provisions of 35 U.S.C. § 112, first paragraph.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Toni R. Scheiner

Administrative Patent Judge

Donald E. Adams

Administrative Patent Judge

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BOARD OF PATENT

) APPEALS AND

) INTERFERENCES

Eric Grimes

Administrative Patent Judge

Appeal No. 2004-1103 Application No. 09/733,387

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